

## EC-Declaration of Conformity

according to directive 98/79 EC on in vitro diagnostic medical devices

We, as manufacturer

Chromsystems Instruments & Chemicals GmbH  
Am Haag 12  
82166 Gräfelfing, Germany

declare on our own responsibility, that herein after called in vitro diagnostic medical devices for the LC-MS/MS determination of:

GMDN Code 64333, term "Multiple antipsychotic therapeutic drug monitoring IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

EDMA Nomenclature term: Other Central Nervous System TDM  
EDMA Nomenclature code: 12-08-02-90-00  
IVDD Classification: other product

Reagent Kit: 92914/XT2 - **MassTox**® TDM Series A PARAMETER-Set  
Neuroleptics 2/EXTENDED 2 in Serum/Plasma

Calibrator: 92026/XT2 - 3PLUS1® Multilevel Plasma Calibrator Set **MassTox**®  
Neuroleptics 2/EXTENDED 2

Controls: 0227/XT2 - **MassCheck**® Neuroleptics 2/EXTENDED 2 Plasma Control,  
Bi-Level (I + II)  
0228/XT2 - **MassCheck**® Neuroleptics 2/EXTENDED 2 Plasma Control,  
Level I  
0229/XT2 - **MassCheck**® Neuroleptics 2/EXTENDED Plasma Control,  
Level II

Products:  
92046/N2/XT2 - Internal Standard Set **MassTox**®  
Neuroleptics 2/EXTENDED 2  
92017/XT2 - Tuning Mix **MassTox**® Neuroleptics 2/EXTENDED 2

meet all applicable requirements of the directive 98/79/EC.

Conformity assessment procedure: Annex III of the directive 98/79/EC

Applied harmonized standards:

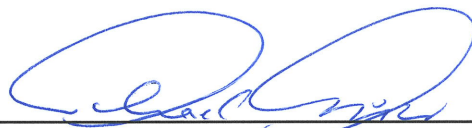
EN ISO 13485, EN 13612, EN 13641, EN ISO 14971, EN 18113-1, EN 18113-2,  
EN 15223-1, EN 17511, EN 23640

# CHROMSYSTEMS

DIAGNOSTICS BY HPLC & LC-MS/MS

Notified body: -

Gräfelfing, May 02<sup>nd</sup>, 2022



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Michael Meier, Managing Director

EC declaration valid until May 26<sup>th</sup>, 2027

Vers. 3.0